

### FORWARD LOOKING STATEMENTS

Except for the historical information set forth herein, the matters set forth in this presentation, including statements regarding the potential for growth and diversification of Incyte's revenues; the "peak sales" estimates for Incyte's products; Incyte's strategy for addressing GVHD; whether or when Jakafi®, on its own or in combination with another therapy, such as axatilimab, might provide a successful treatment option for patients with GVHD; whether and when axatilimab, whether on its own or in combination with another therapy, might provide a successful treatment option for patients with chronic GVHD; when updated clinical trial results for axatilimab might be available; and Incyte's expectations regarding its collaboration with Syndax and the possible opportunities presented by that collaboration, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte's clinical trials supply chain and other third-party providers and development and discovery operations; determinations made by the FDA or other regulatory authorities; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. Incyte disclaims any intent or obligation to update these forward-looking statements.



# HERVÉ HOPPENOT

CHIEF EXECUTIVE OFFICER, INCYTE



# GROWING AND DIVERSIFYING REVENUES

PORTFOLIO OF 5 PRODUCTS + ROYALTIES WITH SIGNIFICANT UPSIDE POTENTIAL

### **New Approvals**





MPN/GVHD franchise	MF, PV, GVHD	\$3+ Billion U.S.
Opzelura™ (ruxolitinib) cream 1.5%	2L Atopic Dermatitis	<b>\$1.5+ Billion</b> U.S.
MONJUVI® tafasitamab-cxix   200 mg for injection, for intravenous use	2L DLBCL	<b>\$500 - \$750 Million<sup>2</sup></b> U.S.
MINJUVI® tafasitamab	2L DLBCL	N/A
Pemazyre: (pemigatinib) tablets	2L Cholangiocarcinoma/BTC <sup>3</sup>	N/A
o ICLUSIG™	CML	N/A

**Peak Sales Guidance** 



MF = myelofibrosis; PV = polycythemia vera; GVHD = graft-versus-host disease; DLBCL = diffuse large B-cell lymphoma; CML = chronic myeloid leukemia; Monjuvi (tafasitamab-cxix) is a registered trademark of MorphoSys.

(ponatinib) tablets

1. Development of ruxolitinib in GVHD in collaboration with Novartis; 2. Monjuvi revenues as recognized by MorphoSys; 3. Pemazyre is approved for cholangiocarcinoma in the US and in Europe and is approved in Japan in biliary tract cancer

## CHRONIC GVHD STRATEGY ACROSS ALL LINES OF THERAPY

PURSUING COMPLEMENTARY PATHS TO ADDRESS PATIENTS IN NEED OF THERAPEUTIC OPTIONS

1<sup>st</sup> Line 2<sup>nd</sup> Line 3<sup>rd</sup> Line Acute lakafi® **GVHD** 50% progress on corticosteroids ~3,000 ruxolitinib (tablets) U.S. prevalence Jakafi® **GRAVITAS**-309 Chronic ruxolitinib (tablets) Phase 3 trial of itacitinib + **GVHD** axatilimab corticosteroids vs. corticosteroids ~14,000 monotherapy U.S. prevalence Potential for Potential for axatilimab + JAK inhibition axatilimab + JAK inhibition



# PETER LANGMUIR

**GROUP VICE PRESIDENT, ONCOLOGY TARGETED THERAPEUTICS** 



## GVHD IS A MAJOR CAUSE OF MORBIDITY AND MORTALITY

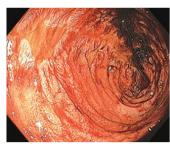
### **Acute GVHD**

Poor prognosis for acute GVHD patients, especially for the ~40% of patients with initial Grade III-IV disease<sup>1</sup>

Acute Grade (% of total) <sup>4</sup>	Survival at Year 1 <sup>5,6</sup>
Grade II (60%)	75%
Grade III (25%)	51%
Grade IV (15%)	24%

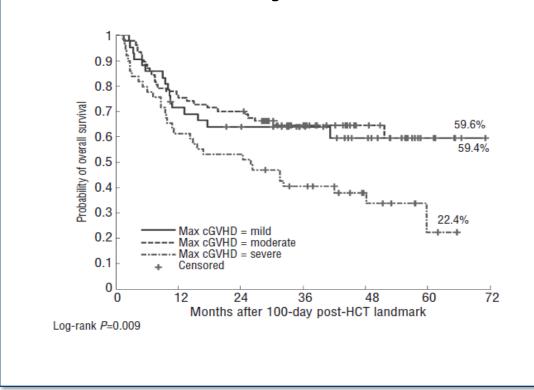
Failure to respond to initial steroid therapy is the most significant predictor of non-relapse mortality at 2 years (N = 287; HR = 0.4, P < 0.001)<sup>7</sup>





### **Chronic GVHD**

Approximately 20-30% of patients have severe chronic GVHD and are therefore at significant risk of death<sup>2,3</sup>





- 1. MacMillan et al Biology of Blood and Marrow Transplantation (2002); 8:387-394 2. Arai et al Biology Blood Marrow Transplant. (2015); 21(2): 266–274
- 3. Pidala et al Haematologica (2011) 96(11) 1678-1684
- 4. 1L acute GVHD defined as Grade II-IV; Grade I acute GVHD is either untreated or treated with oral steroids, no systemic treatment (Khoury et al Hematologica (2017) 102 (5):958-966)
- 5. Rowlings et al. British Journal of Haematology, 1997, 97, 855-864; 6. Khoury et al Hematologica (2017) 102 (5):958-966 7, Westin JR, Adv Hematol, 2011;2011;e601953

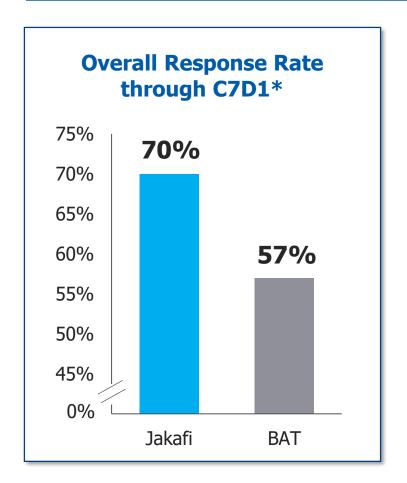
# JAKAFI®: NOW APPROVED FOR CHRONIC GVHD IN 2L

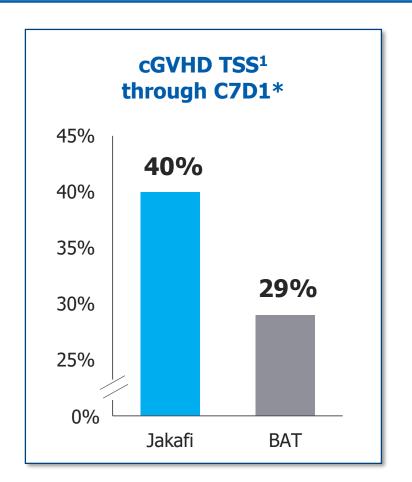


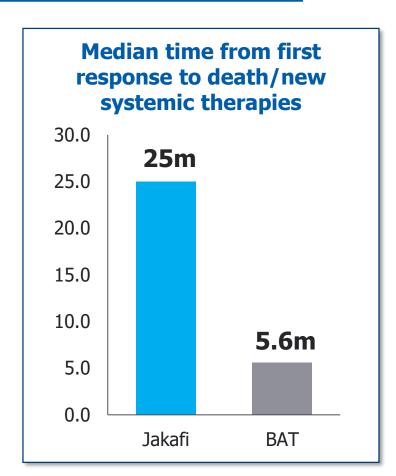
Now approved for the treatment of chronic graft-versus-host disease after failure of one or two lines of systemic therapy ruxolitinib (tablets) in adult and pediatric patients 12 years and older

Acute Chronic **Polycythemia Myelofibrosis Graft-vs-Host Graft-vs-Host** Vera Disease **Disease** Approved indications

## JAKAFI® U.S. cGVHD LABEL: SAFETY AND EFFICACY DATA



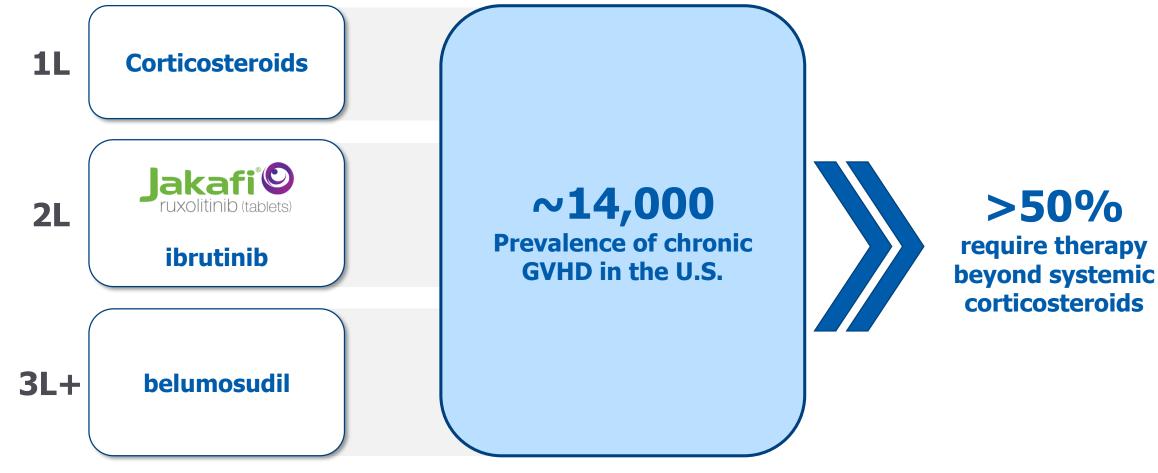




Most common hematologic adverse reactions (incidence ≥35%) are anemia and thrombocytopenia



# SIGNIFICANT NEED FOR THERAPY BEYOND STEROIDS





Source: DRG.

# AXATILIMAB: ANTI-CSF1R MAB TARGETING MACROPHAGE DRIVEN DISEASES

### CSF-1 CSF-1R Monocyte **Blood vessel** Circulating Monocyte CSF-1R CSF-1R Circulating CSF-1R Monocyte macrophage acrophage **FIBROSIS** Fibroblasts Tissue Collagen

### Potential for axatilimab + JAKi combinations

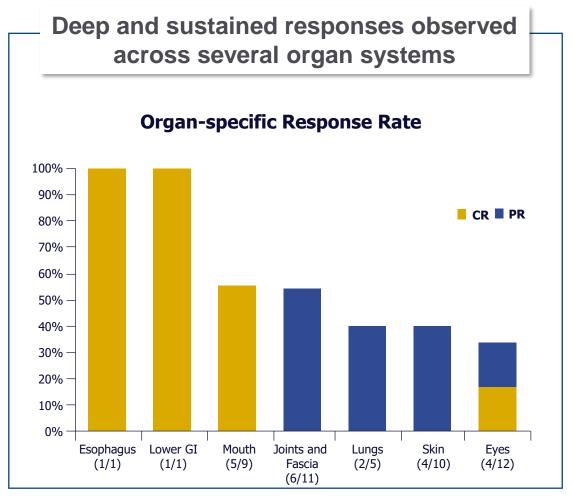
- Complementary effects on inflammatory pathways involved in GVHD pathogenesis
  - Axatilimab depletes monocytes
  - ✓ JAKi block T-cell mediated inflammatory cytokines
- Potential for 1L steroid-free regimen in combination with JAK inhibitors

### **Next Steps**

- P1/2 (axatilimab) updated results in Q4′21
- P2 (axatilimab + JAKi) in SR cGVHD planned initiation in '22



## AXATILIMAB: PHASE 1/2 TRIAL ESTABLISHES POC IN cGVHD



Axatilimab demonstrates good tolerability with clinical activity demonstrated by a 57% (n=8) response rate in a heavily treated patient population





# **CONCLUSION**

- JAKAFI® received full approval for steroid-refractory chronic GVHD
- Significant unmet need in chronic GVHD; Poor prognosis for many patients living with GVHD
  - 50% of patients need therapies beyond systemic corticosteroids
  - Many patients become steroid-dependent and develop toxicity due to chronic steroid use
- Syndax collaboration allows for potential combination therapy in chronic
   GVHD in the 1L and 2L+ settings



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# OPPORTUNITY TO EXPAND INTO MULTIPLE LINES OF TREATMENT FOR cGVHD IN US AND EX-US MARKETS

### **Deal Terms & Financials**

- Upfront payment of \$117m cash and \$35m equity investment to Syndax<sup>1</sup>
- Incyte leads global commercial activities and records revenues worldwide
  - > **U.S.:** 50:50 profit share
  - **Ex-US:** Double-digit royalties paid to Syndax
- Syndax to fund 45% of global collaboration studies

#### **Rationale**

- Expand and maximize complementary axatilimab program in cGVHD
  - Opportunities for monotherapy and combination therapy across multiple lines of GVHD treatment
  - US and ex-US development and commercialization
- ✓ Option to co-develop axatilimab in idiopathic pulmonary fibrosis (IPF)
- ✓ Leverages commercial capabilities

